DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

February 22, 2005

FILE COPY

Deborah A. Jaskot
Vice President, Regulatory Affairs
Teva Pharmaceuticals USA
1090 Horsham Road
North Wales, PA 19454

Dear Ms. Jaskot:

Your petition requesting the Food and Drug Administration to determine whether Vioxx Tablets, manufactured by Merck has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons, was received by this office on 02/22/2005. It was assigned docket number 2005P-0079/CP 1 and it was filed on 02/22/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0079

ACK 1